

# A Survey of Experiences and Opinions Regarding Skin Toxicities Associated with Vectibix Among mCRC Patients

**First published:** 30/07/2019

**Last updated:** 11/11/2020

Study

Finalised

## Administrative details

### EU PAS number

EUPAS30334

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### Study ID

38009

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

This descriptive study is designed with the primary objective of assessing experiences and opinions regarding dermatologic toxicities that may develop among mCRC patients who are treated with and without Vectibix.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Amgen

United States

**First published:** 01/02/2024

**Last updated:** 21/02/2024

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

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Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

# Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 01/03/2019

Actual: 15/03/2019

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### **Study start date**

Planned: 01/11/2019

Actual: 01/11/2019

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### **Data analysis start date**

Planned: 01/01/2020

Actual: 15/11/2019

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### **Date of final study report**

Planned: 30/06/2020

Actual: 11/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

# Study protocol

[csr-20190025-protocol\\_public-redacted-approved-version.pdf](#) (926.35 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Human medicinal product

Disease /health condition

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Disease epidemiology

**Data collection methods:**

Primary data collection

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**Main study objective:**

To assess the experiences and opinions regarding dermatologic toxicities that may develop among mCRC patients who are treated with and without Vectibix.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

VECTIBIX

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**Medical condition to be studied**

Skin toxicity

## Population studied

**Short description of the study population**

Patients needed to be at least 18 years of age, have a diagnosis of metastatic colorectal cancer (mCRC) and provide consent to participate.

**Inclusion Criteria**

1. 18 years of age or older

2. Have a self-reported physician diagnosis of mCRC

3. Have consented to participate

#### Exclusion Criteria

Patients not meeting inclusion criteria will be excluded. Additional exclusion criteria include treatment with cetuximab at any point.

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#### Age groups

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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#### Special population of interest

Other

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#### Special population of interest, other

Metastatic colorectal cancer (mCRC) patients

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#### Estimated number of subjects

200

## Study design details

#### Outcomes

Among mCRC Vectibix patients • Describe mCRC patient opinions regarding the risk of skin • Characterize the timing and severity of rash • Describe the education they received to prevent and manage rash • Describe management strategies • Describe the impact on quality of life  
Among mCRC non-Vectibix

patients • Describe patient opinions regarding the risk of skin rash

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### **Data analysis plan**

The following descriptive statistics will be analyzed: • Proportion of mCRC patients who agree to participate in the study • Proportion of mCRC patients who meet the criteria for participation (i.e. eligibility rate) The consent rate will be calculated as the proportion of eligible patients who consent to participate in the survey out of all eligible patients.

## Documents

### **Study results**

[20190025\\_Adelphi ORSR\\_08.24.20\\_abstract \(002\)\\_Redacted.pdf](#) (38.69 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data sources (types)**

[Other](#)

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## **Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No